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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/863,823
Filing Date: May 23, 2001
Appellant(s): WALKE ET AL.

David W. Hibler
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 24 October 2005 appealing from the Office action mailed 19 May 2003.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

Appellants know of no related appeals or interferences.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. The amendment filed on 22 August 2003 has been entered. Accordingly, the rejection of claim 2, made under 35 U.S.C.§ 112, second paragraph, has been withdrawn.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be reviewed at Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

U.S. Patent 5,445,934

U.S. Patent 5,556,752

U.S. Patent 5,744,305

U.S. Patent 5,837,832

U.S. Patent 6,156,501

U.S. Patent 6,261,776

U.S. Patent 5,817,479

U.S. Patent 5,654,173

U.S. Patent 5,552,281

U.S. Patent 6,340,583

GenBank Accession Numbers AC087644 and AC090685;

Venter et al., 2001, Science 291:1304

lasny and Kennedy, 2001, Science 291:1153;

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC §101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9a. Claims 1-4 and 6-13 stand rejected under 35 U.S.C. § 101, for reasons of record, set forth in the office action mailed on 09/25/02, pages 4-8 and reiterated in the office action mailed on 05/19/03, pages 2-7, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-4 and 6-13 of the instant invention are directed to isolated nucleic acid molecule comprising a nucleotide sequence encoding the polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2 or 6, said nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:1, and an isolated nucleic acid encoding the polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2 that also hybridizes under specific recited stringent conditions to the nucleotide sequence set forth in SEQ ID NO:I.

The specification describes the claimed nucleic acid molecule as encoding novel human proteins (NHPs) which have structural similarity with eukaryotic membrane and secreted proteins, including , but not limited to neural cell adhesion molecules (NCAM), tyrosine kinase receptors and vascular endothelial growth factor (VEGF) receptors, (page 1, lines 25-31 and page 2, lines 1-6). The instant specification discloses a deduced amino acid sequences for the NHP encoded by the claimed nucleic acid and states that the NHPs can be expressed in several human tissues, but mainly in the kidney, as well as gene trapped human cells, (see page 16, lines 15-21). The specification further describes tim NHP encoded by the claimed nucleic acid as sharing significant similarity with neural cell adhesion molecules, via the lg-like domain, (see page 16, lines 23-24). However, instant specification does not disclose how much structural similarity is there between the claimed protein and NCAMs, and whether the claimed protein has activity and biological function similar to that of NCAM. Furthermore, Applicants do not establish whether having an lg-like domain assures a specific function and activity for the NHP encoded by the claimed nucleic acid. It is also

unclear whether the NHP encoded by the claimed nucleic acid has more structural and functional identity to the NCAMs than it is to the tyrosine kinase receptors or VEGF receptors. Instant specification does not provide any information regarding physiologic or functional characteristics of NHPs, encoded by the claimed nucleic acid molecule. Furthermore, the NHP encoded by the claimed nucleic acid has never been expressed, no biological activity was assayed or determined for it and only it's deduced amino acid sequence and general methods of expressing recombinant proteins is disclosed. Instant specification asserts that the claimed nucleic acid sequences can be utilized in micro arrays or other assay formats to screen of genetic material from patients who have particular medical condition, (see page 7, lines 24-28). However, the particular medical conditions that can be diagnosed using the claimed nucleic acid are not disclosed, thus the skilled artisan would not know\v which medical conditions, can be diagnosed using the claimed nucleic acid or the encoded protein. While, the instant specification asserts that the NHP encoded by the claimed nucleic acid can be used to treat disorders, and discloses conventional protein administration techniques, it does not disclose specific diseases which can be treated or diagnosed using the NHP protein encoded by file claimed nucleic acids. The specification establishes no connection between any physiological condition or disorder and this protein, i.e. is the NHP of the instant application over expressed, under expressed or completely lacking in any disorder? The specification provides no working examples as to the activity of the NHP encoded by the claimed nucleic acids, and one of ordinary skill in the art would not be able to predict what activity would be possessed by the protein of the instant application based solely

because it might be related mammalian neural cell adhesion molecules (NCAM), tyrosine kinase receptors or vascular endothelial growth factor (VEGF) receptors.

Furthermore, members of each of the above-mentioned protein families have disparate but equally important functions. For example, the proper development of the central nervous system depends upon the temporally and spatially-regulated expression of neural cell adhesion molecules (NCAMs), which consists of several families of membrane proteins that are particularly important for pathway development and establishment of appropriate synaptic. Failure of NCAMs to function appropriately during development results in a spectrum of deficits ranging from gross malformations to subtle psychomotor retardation. Receptor tyrosine kinases (RTK)s are high affinity cell surface receptors for many polypeptide growth factors, cytokines and hormones. Receptor tyrosine kinases have been shown to be not only key regulators of normal cellular processes but also to have a critical role in the development and progression of many types of cancer. Finally, Vascular endothelial growth factor (VEGF), a potent mitogen of endothelial cells, is produced in elevated amounts by many tumors, including ovarian carcinomas, induces angiogenesis and endothelial cell proliferation upon binding to its receptor, and also plays an important role in regulating vasculogenesis. Thus, one of skill in the art would not be able to predict which of these functions or activities would the NHP encoded by the claimed nucleic acid exhibit. Accordingly, the specific biological role of the claimed protein can not be ascertained. The instant specification does not disclose any information regarding the biological activity or functional data of the protein encoded by the claimed nucleic acid, therefore, using it as

a research tool to develop therapeutics does not provide it with a substantial or specific utility, because, one of ordinary skill in the art would not know which diseases to target. Another asserted utility is to use the claimed nucleic acid and the encoded protein as reagents in diagnosis assays for the identification of other cellular gene products related to NHP, however, since the specification fails to disclose any physiological condition or specific disorders that this nucleic acid and the protein it encodes are involved in, this utility is neither substantial nor well-established. Therefore, the claimed nucleic acid and the encoded polypeptide do not have a substantial utility because basic research is required to study the properties and activity of the claimed polynucleotide and the encoded protein.

The claimed invention is directed to a polynucleotide encoding a polypeptide of as yet undetermined function or biological significance, therefore, unless Applicants demonstrate the physiological significance or the biological role of the instant polynucleotide and the protein it encodes, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9b. Claims 1-4, 6-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and

substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification only discloses the structure of the nucleic acid molecule of SEQ ID NO:1 and 5, and discloses a deduced amino acid sequence for the encoded proteins, however, it does not disclose an activity for the encoded protein, and only states that it shares structural similarity with neural cell adhesion molecules (NCAM), tyrosine kinase receptors or vascular endothelial growth factor (VEGF) receptors. Therefore the skilled artisan would not know how to use the nucleic acid molecule of SEQ ID NO:I, 5 or the encoded proteins.

(10) **Response to Appellants' Arguments:**

On pages 4-5 of the Brief, Appellants argue that the claimed sequences have utility in diagnostic assays, such as forensic analysis, because the specification discloses two coding single nucleotide polymorphisms, specifically, a G/C polymorphism at position 212 of SEQ ID NO: 1, which can lead to a glycine or alanine residue at amino acid position 71 of SEQ ID NO:2, and an A/C polymorphism at position 219 of SEQ ID NO: 1, which can lead to a lysine or asparagine residue at amino acid position 73 of SEQ ID NO:2. Appellants argue that the Examiner's argument that "associations between a disease and specific differences (SNPs) in a population" are not disclosed in the specification, mischaracterizes Appellants' position. Appellants point out that the use of the presently described polymorphisms in forensic analysis does not require the identification of a specific medical condition. Rather, the presently described polymorphisms are useful in forensic analysis, since polymorphisms are the basis for

forensic analysis, which is a "real world" utility, thus, the claimed sequence must in itself be useful in forensic analysis to distinguish individual members of the human population from one another based simply on the presence or absence of one or more of the described polymorphisms. Appellants assert that the claimed nucleic acid can be used for forensic analysis to distinguish 50% of the population and the skilled artisan would be able to use the presently described po!ymorphisms in forensic analysis without any additional research. It is important to note that simply because the use of these polymorphic markers will necessarily provide additional information on the percentage of particular subpopulations that contain these polymorphic markers does not mean that additional research is needed in order for these markers as they are presently described in the instant specification to be used in forensic science.

This argument has been fully considered, but is not deemed persuasive. Initially, using the claimed nucleic acids for forensic analysis to distinguish individual members of the human population based on the presence or absence of one or both of the described polymorphisms does not afford the claimed nucleic acids specific and substantial utility, because the specification does not clearly provide any guidance as to how one skilled in the art would use such information. The nucleic acids in question are not shown to be associated with any specific disease condition or a racial or genetic group of individuals. Without such guidance one skilled in the art would have to do further research in order to correlate said polymorphism to a group or disease or any special characteristic. Therefore this is not a specific utility for the claimed nucleic acid. Furthermore, Appellants have not established the significance of the presence or

absence of the claimed nucleic acid in a subject. The mere presence or absence of the claimed nucleic acid in a subject is not a substantial utility, because any DNA can be used for said general purpose. In order for the presently claimed nucleic acid to be useful in forensic analysis, it must provide significant information about an individual, other than its presence or absence in said individual. There is no doubt that SNP research is a significant and emerging field. For example, the presence of a specific SNP can be used to identify those individuals who are likely to benefit from a new medication, from those who could suffer adverse side effects or to determine the optimal dosage. However, in the instant case, Applicants have not shown that the claimed nucleic acid can be used in any meaningful way, other than that it may distinguish 50% of the population as having it. Does this mean that those individuals that have it: are susceptible to certain diseases, are unique and can be solely identified because of the presence of said DNA?

On pages 6-8 of the Brief, Appellants argue that the requirement for a specific utility, which is the proper standard for utility under 35 U.S.C. § 101, should not be confused with the requirement for a unique utility, which is clearly an improper standard. The fact that other polymorphic markers have been identified in other genetic loci, or that the use of the presently described polymorphic markers will provide additional information concerning the prevalence of these markers in certain subpopulations, would not mean that use of the polymorphic markers identified by Appellants' in SEQ ID NO: 1 in forensic analysis is not a specific utility. Appellants cite in re Carl Zeiss Stiftung v. Renishaw PLC, 20 USPQ2d 1101 (Fed. Cir. 1991; "'Carl Zeiss"). Appellants submits

that just because other (possibly better) polymorphic markers from the human genome have been described, or that additional information about the presently described polymorphic markers can be gained through the use of these markers, does not establish that the presently described polymorphic markers lack a specific utility. Appellants further argue that If every invention were required to have a unique utility, the Patent and Trademark Office would no longer be issuing patents on batteries, automobile tires, golf balls, golf clubs, and treatments for a variety of human diseases, such as cancer. Appellants cite in re Brana and remind the Office that FDA approval is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions.

These arguments have been fully considered, but are not deemed persuasive. While each and every composition does not have to be unique in order for it to be patented, it has to have a specific and substantial utility. The skilled artisan must know how to use said composition. Novel golf balls, automobiles and batteries must provide a useful improvement over already existing golf balls, automobiles and batteries, in order to satisfy the requirements under 35 U.S.C.§ 101. Appellants are mischaracterizing the Office's position, because the issue in the instant case is not, whether other polymorphic markers from the human genome have been described, or whether additional information about the presently described polymorphic markers can be gained through the use of these markers, however, the issue is that the mere presence or absence of the claimed nucleic acid in a subject is not substantial or specific utility, because ***any*** DNA can be used for such general purpose. Furthermore,

as stated earlier, without knowing what the significance of the existence of the said nucleic acid is in an individual or what characteristic is associated with said nucleic acid, one skilled in the art would not know how to use the polynucleotide. In other words, the presently claimed nucleic acid does not provide significant information about an individual, other than that it is either present or absent in said individual. Regarding, Appellants' argument based on *Carl Zeiss Stifung vs Renishaw*, the fact pattern of the instant case differs from that of the cited case. The instant case does not disclose any specific or substantial utility, only general utility that can be applied to any nucleic acid. Furthermore, the courts have held that,

> "A specific utility" is specific to the subject matter claimed and can "provide a well-defined and particular benefit to the public." In re Fisher, 421 F.3d 1365, 1371, 76 USPQ2d 1225, 1230 (Fed. Cir. 2005).

This contrasts with a general utility that would be applicable to the broad class of the invention.

Moreover, although the need for further research does not necessarily equate to lacking utility, in the instant case, Appellants have not provided one single specific and substantial utility for the claimed nucleic acid, other than general uses that are applicable to all DNAs. With respect to in *re Brana*, 34 USPQ 1436, 1441 (Fed. Cir. 1995), *Brana* disclosed compounds with specific structure and specific activity. Thus, in that case evidence of success in structurally similar compounds was relevant in determining whether one skilled in the art would believe an asserted utility; therefore, an implicit assertion of a tumor target was sufficiently specific to satisfy the threshold utility requirement. Furthermore, in *re Brana*, there were test results showing that several

compounds within the scope of the claims exhibited significant antitumor activity against standard tumor model in vivo. However, the instant Appellants only provides general utility that can be applied to any nucleic acid. Finally, While the FDA approval is not a prerequisite for finding a compound useful within the meaning of the patent laws, and the requirement for the utility of the claimed invention is different from the FDA standard for drug approval, 35 U.S.C. §101 does require a specific, substantial, and credible utility, or well-established utility for an invention. Such a utility has to be a "real world" context of use, which does not require significant further research. Appellants seem to confuse this requirement with the "further research and development" needed in pharmaceutical composition and drug development. In other words, a patentable utility has to be clearly identified or immediately apparent in the specification, whereas some "further research and development" is permitted in drug development. For example, determining optimal dosages or drug tolerance in humans is further research and development, which is acceptable under 35 USC §101 because it is not significant. On the other hand, determining a specific disease to be treated by a drug constitutes significant further research and development, which is not acceptable under 35 U.S.C. § 101. In the instant case, the specification fails to disclose a specific physiological significance for the claimed nucleic acids, other than they can be used in forensic analysis, a utility that is applicable to all nucleic acids.

On pages 9-11 of the Brief, Appellants argue that although they need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101, the specification detailed an additional example of the utility that the present nucleotide

sequences have utility in assessing gene expression patterns using high-throughput DNA chips and Appellants cite several patents that pertain to DNA Chips. Appellants submits that evidence of the "real world substantial utility" of the present invention is further provided by the fact that there is an entire industry established based on the use of gene sequences or fragments thereof in a gene chip format. Appellants assert that an entire industry is established based on the use of gene sequences in gene chip format, and Appellants cites few well known companies such Affymetrix, Gene Logic, ABI-Perkin-Elmer, HySeq and Incyte. Applicant also argues that real world "substantial" utility for the claimed sequence is provided by the fact that Rosetta Inpharmatics, a gene company was acquired by Merck & Co, for the substantial sum of money, $620 million. Appellants contend that given the widespread utility of such "gene chip" methods using public domain gene sequence information, there can be little doubt that the use of the presently described novel sequences would have great utility in such DNA Chip applications. Appellants further submit that persons of skill in the art, as well as venture capitalists and investors, readily recognize the utility; both scientific and commercial, of genomic data in general, and specifically human genomic data. Billions of dollars have been invested in the human genome project. Appellants cite Venter et al., 2001, Science 291:1304; and Jasny and Kennedy, 2001, Science 291:1153, which pertains to the success of the human genomic data. Appellants argue that the present sequences are specific markers of the human genome and are targets for the discovery of drugs that are associated with human disease, those of skill in the art would instantly recognize that the present nucleotide sequences would be ideal, novel candidates for

assessing gene expression using such DNA chips.

This argument has been fully considered, but is not deemed persuasive. It is acknowledged that the function of a particular nucleic acid may not be necessary for said nucleic acid to be used in a gene chip, however, the significance of the altered levels or forms of a gene in a tissue compared to another tissue, must be known. Furthermore, Appellants have not disclosed any conditions or reasons in which it might be desirous to increase or decrease the claimed nucleic acid. Therefore, following the expression levels of a nucleic acid without the knowledge of the conditions and circumstances that would lead the skilled artisan to increase or decrease it, would be meaningless. Furthermore, since any expressed polynucleotide can be used for gene expression monitoring, the asserted utility is not specific to the claimed nucleic acids. The specification does not disclose that the claimed nucleic acid is a marker for specific diseases. Absent a disclosure of altered levels or forms of a gene in diseased tissue as compared with the corresponding healthy tissue, the gene is not a disease marker or an appropriate target for drug discovery or toxicology testing. The fact that there is an entire multi billion dollar industry based on gene chip technology and patents issued to gene chip inventions does not provide the claimed invention with a specific or well established utility, because this revolutionizing technology enables scientists to attain ambitious goals from identifying genetic variations associated with disease to discovering new drug targets. The instant application is not drawn to a novel gene chip technology, but rather to nucleic acid sequences with no known physiological role. As was set forth above, this invention is not drawn to a novel gene chip technology;

therefore, arguments and references pertaining to the success of the gene chip technology are irrelevant for the claimed invention. Finally, evidence of commercial success, while sometimes persuasive as secondary evidence of non-obviousness, is immaterial to utility and enablement. Many products have enjoyed commercial success due to fads or clever advertising, wherein the products would not have met the legal standards for utility and enablement.

On pages 10-11 of the Brief, Appellants argue that the Examiner is requiring that one must know the biological significance of the polynucleotides which are being evaluated, and that without this information, the results of the transcript image are useless because one would not know if the polynucleotide expression should be increased or decreased. Appellants point out that the nucleic acid sequences are commonly used in gene chip applications without any information regarding the function of the encoded protein, or even evidence regarding whether the sequence is actually even expressed. Appellants further submit that the present sequence, which has been biologically validated to be expressed, has a much greater utility than sequences that are merely predicted to be expressed based on bioinformatic analysis. Appellants also argue that expression profiling does not require knowledge of the function of the particular nucleic acid on the chip, rather the gene chip indicates which DNA fragments are expressed at greater or lesser levels in two or more particular tissue types. Appellants point out that although further information regarding the biological activity of a particular nucleic acid sequence might make it even more useful in gene chip applications, this does not mean that the use of the presently claimed nucleic acid

sequence in gene chip applications is not a specific utility. Appellants contend that the fact that other expressed sequences can be used to track gene expression, or that additional information concerning the presently claimed sequence might make it even, more useful in certain gene chip embodiments, does not mean that the use of Appellants' sequence to track gene expression on a gene chip is not specific utility.

This argument has been considered, but is not deemed persuasive. The Appellants criticize the examiner's position that the claimed polynucleotide cannot be useful without precise knowledge of its biological function. However, Appellant is mischaracterizing the examiner's position. A specification can meet the legal requirements of utility and enablement for a new polynucleotide as long as the specification discloses a credible, specific and substantial asserted utility for the new polynucleotide, or a well-established utility for the claimed polynucleotide. A hypothetical example may serve to clarify. For example, a hypothetical specification discloses that a claimed polynucleotide is closely linked chromosomally to a known disease, and that there is a restriction fragment length polymorphism for the polynucleotide which co-segregates with the disease. Therefore, the polynucleotide may be used to detect individuals carrying the disease gene. The hypothetical specification does not disclose the biological activity of the polypeptide encoded by the polynucleotide. The claimed polynucleotide in the hypothetical example would not be rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as it has utility and is enabled as a disease marker. However, such is not the fact pattern here. The instant specification discloses that the claimed polynucleotides can be used in a gene chip,

however, there is no sufficient disclosure that the claimed polynucleotide or the encoded polypeptides are expressed at altered levels or forms in any specific, diseased tissue. Thus, this is not specific utility, since any nucleic acid can be used in DNA chips.

On pages 11-13 of the Brief, Appellants argue that another specific utility for the claimed nucleic acids is in "identification of coding sequence" and "mapping a unique gene to a particular chromosome". Applicants argue that the claimed nucleic acids have utility, not because they can be used to produce the encoded protein, but because they provide biologically validated empirical data that specifically define that portion of the corresponding genomic locus which actually encodes the exon sequence. Also significant is that the claimed sequences define how encoded exons are actually spliced together to produce active transcripts. Thus Applicants submit that the practical scientific value of biologically validated, expressed, spliced and polyadenylated mRNA sequences is readily apparent to those skilled in the art. Applicants also argue that the claimed nucleic acids provide exquisite specificity in localizing the specific region of human chromosome 17 that contains the gene encoding the given polynucleotide, a utility not shared by virtually any other nucleic acid sequences. Applicants state that Venter et al demonstrates the significance of expressed sequence information in the structural analysis of genomic data.

This argument is not found persuasive. Using the claimed nucleic acid as a chromosomal marker does not provide the claimed invention a specific utility, **because no meaningful information will be obtained from tracking the level of expression of the claimed nucleotide and because there is no physiological or biological**

significance attached to these nucleotides or the encoded proteins. Without a disclosure of a particular disease state in which the claimed nucleic acid is expressed at an altered level or form, it would be impossible to determine what the results of a gene expression monitoring assay mean. For example, if a compound is tested on a microarray comprising the claimed nucleic acid and affects expression of the nucleic acid negatively, it cannot be determined if that means that the compound is a potential good drug for a disease or would acerbate the disease if administered. The test results also would not have meaning in terms of what specific disease is relevant. The relevance of Applicants' citation of Venter et al (Science Vol.291, pages 1304-1351, 2001) is not clear. Venter's reference is about decoding and sequencing the human genome. Venter discloses that only 1% of SNPs results in variation in proteins, and that the task of determining which SNPs have functional consequences remains an open challenge, (see abstract). Therefore, since Applicants have not disclosed the physiological relevance of the claimed nucleic acid, one of ordinary skill in the art would not know how to use it.

Furthermore, the fact that the claimed nucleic acid encodes a sequence and can be used to identify how exons are actually spliced together to produce an active transcript does not provide the claimed nucleic acid a specific and substantial utility. The instant claims are drawn to nucleic acid molecules, not to methods of specifically defining portions of a gene that actually encodes a sequence. Finally, Applicants are correct in that the assertion of one credible utility is needed to meet the requirement under 35 U.S.C.§ 101, however, said utility must also be specific and substantial (real

world use). The instant case fails to disclose a specific and substantial use for the claimed nucleic acid, because there is no biological significance or correlation to a specific disease state attached to said nucleic acid.

On pages 14-15 of the Brief, Appellants argue that the current rules and regulations regarding the examination of patent application is and always has been as set forth in 35 U.S.C . and patent rules as set forth in 37 C.F.R, and not the manual of patent examination procedures or particular guidelines for patent examination. Furthermore, Applicants submit that it is the job of the judiciary and not the USPTO to interpret these laws and rules. Again applicants cite various new patents that were recently issued, and contend that it is capricious and arbitrary to hold the instant Applicants on a different standard.

This argument is not found persuasive. The Examiner is only applying and enforcing the requirements under 35 U.S.C.§ 101, which require that an invention must not only be novel but must also be useful. The contents of 35 U.S.C, 37 C.F.R, judicial decisions, and guidelines established by the USPTO are not subject to examiner review and will not be questioned or defended by the Examiner. These decisions were made by legally empowered government entities to which the Examiner is subordinate and those decisions will be followed without question by the examining corps. Finally, Appellants are reminded that each Patent Application is examined on its' own merits and each Patent Application must meet the criteria set forth in the Revised Interim Utility Guidelines, for a specific and substantial credible asserted utility, or a well established utility.

For all of these reasons, the rejection claimed invention made under 35 U.S.C. §101 and §112 is maintained.

(11) Related Proceedings Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Fozia Hamud/

Conferees:

/Manjunath N. Rao, /
Supervisory Patent Examiner, Art Unit 1647

/Gary B. Nickol /

Supervisory Patent Examiner, Art Unit 1646